Calendar No. 603

100TH CONGRESS
2d Session

SENATE

REPORT
100-310

ORGAN TRANSPLANT AMENDMENTS ACT OF 1987

MARCH 29 (legislative day, MARCH 21), 1988.—Ordered to be printed

Mr. KENNEDY, from the Committee on Labor and Human Resources, submitted the following

REPORT

together with

ADDITIONAL VIEWS

[To accompany H.R. 3097]

The Committee on Labor and Human Resources, to which was referred the bill (H.R. 3097) to amend the Public Health Service Act to revise and extend the program of assistance to organ procurement organizations, and for other purposes having considered the same, reports favorably thereon with an amendment and recommends that the bill as amended do pass.

CONTENTS

		Page
I.	Summary of Bill	1
II.	Background and Need for Legislation	2
III.	Text of Bill as Reported	5
IV.	Committee Views	11
V.	Committee Action	18
VI.	Votes in Committee	18
VII.	Cost Estimate	18
VIII.	Regulatory Impact Statement	20
IX.	Section-by-Section Analysis	20
X.	Additional Views	25
XI.	Changes in Existing Law	27

I. SUMMARY OF THE BILL

The Organ Transplant Amendments Act of 1987, H.R. 3097, amends the Public Health Service Act (PHSA) and refines certain

S543-4

provisions of the National Organ Transplant Act of 1984 (P.L. 98–507). Section 2 reauthorizes the grant program for local organ procurement organizations. It also clarifies that these grants may be used to consolidate and improve existing procurement organizations. Section 3 adds to the current duties of the Organ Procurement and Transplantation Network and requires it to adopt standards for the transportation of organs, as well as for the screening of donated organs to prevent the spread of the acquired immune deficiency syndrome virus. Section 4 directs the Secretary to establish a Bone Marrow Registry by October 1, 1988 and authorizes appropriations for the registry. Section 5 extends the authorization of the Office of Organ Transplantation in the Department of Health and Human Services. Sections 5 and 6 set due dates for reports that the 1984 Act requires. Section 7 establishes the Immunosuppressive Drug Therapy Block Grant Program by amending title XIX of the PHSA; it provides for the allotment of grants to States for the purpose of reimbursing the cost of immunosuppressive drugs for organ transplant recipients. Appropriations for a total of $5,000,000 are authorized for this purpose. This section also designates the officers accountable for transplant center operations and required annual reports.

II. Background and Need for Legislation

Background and need

The transplantation of organs in humans, especially the kidney, the heart, and the liver has, since its beginning in the 1950s, become an accepted and effective means of treating a significant number of patients with life-threatening organ failure. However, a serious problem that affects organ transplantation is the wide gap between the need for organs and the supply of donors. At any one time, there are an estimated 8,000 to 10,000 persons waiting for a donor organ to become available, and these numbers continue to grow.

Another serious problem in transplantation is rejection of the donated organ by the immune system of the recipient. Immunosuppressive drugs have helped organ recipients to achieve immunocompatibility, but the costs of this drug therapy have put its benefits out of reach by many organ recipients.

The National Organ Transplant Act of 1984

The 98th Congress responded to widespread public interest and involvement in and concern about the field of organ transplantation, particularly the shortage of organs and the cost of organ transplant procedures, by enactment of the National Organ Transplant Act of 1984 (P.L. 98–507). In addition to prohibiting the purchase of organs, the act provided for the establishment of grants to organ procurement agencies and a national organ-sharing system. The 1984 act also established a 25-member Task Force on Organ Transplantation with membership representing medicine, law, theology, ethics, allied health, the health insurance industry, and the general public. Also represented were the Surgeon General of the Public Health Service, the National Institutes of Health, the Food

and Drug Administration, and the Health Care Financing Administration.

The Omnibus Reconciliation Act of 1986

The Task Force's mandate was to conduct comprehensive examinations of the medical, legal, ethical, economic, and social issues presented by human organ procurement and transplantation. The Task Force's April 1986 report included recommendations for Federal reimbursement for immunosuppressive drug therapy, a more effective national organ procurement network, operational standards for procurement organizations, and the establishment of written protocols for hospital organ procurement. Several provisions responding to the recommendations were included in the Omnibus Reconciliation Act of 1986 (P.L. 99–509, OBRA '86).

Organ Procurement

Despite the cumulative legislative efforts coupled with those of public and private groups, there is still an organ shortage, and there are still inefficiencies and inequalities in the organ procurement system.

The Organ Transplant Amendments Act of 1987 provides for grants to organ procurement organizations and encourages special projects designed to increase the number of organ donors. The Act also clarifies the service area for organ procurement organizations using a formula with parameters that account for geographical and demographic factors. The Act promotes the use of industrywide standards for transplantation by requiring organ procurement organizations to work with hospitals in establishing protocols for organ procurement, and by requiring procurement organizations to screen organs donated to prevent the spread of the acquired immune deficiency syndrome. In addition, membership and medical criteria are to be established by the Organ Procurement and Transplantation Network (OPTN) for organ procurement organizations. The Bone Marrow Registry will be established to increase the availability of bone marrow donors.

Transplantation and Immunosuppressive Drugs

The cost of immunosuppressive drugs continues to make it difficult for organ recipients to pay for such medications. The Task Force on Organ Transplantation, which assessed immunosuppressive medications used to prevent rejection among transplant recipients, issued its report on Immunosuppressive Therapies in October 1985 and its final report on issues and recommendations concerning organ transplantation in April 1986. Based on current knowledge, according to the Task Force, it is apparent that "except for kidney transplants involving identical twins, some form of lifetime immunosuppressive therapy must be provided to every transplant recipient in order to prevent rejection of the transplanted organ by the recipient's immune system".

Insurance Coverage for Immunosuppressive Drugs

Paying for immunosuppressive drugs for transplant recipients remains a major obstacle in the use of such therapy and sometimes serves as a disincentive for patients to receive a transplant. The

extent of private insurance coverage for outpatient immunosuppressive medications varies. Most Blue Cross/Blue Shield plans, commercial health insurers, and health maintenance organizations (HMOs) offer outpatient drug benefits which would cover immunosuppressive drugs, but not all member or policy holders elect to include such benefits in their health insurance policies. The Task Force on Organ Transplantation in its October 1985 report stated that "the single most significant problem patients face in obtaining immunosuppressive medications is their inability to pay for the drugs because of the high cost of the drugs as well as inadequate or nonexistent insurance coverage." Costs for conventional immunosuppressive drugs, as taken by the patient after leaving the hospital, average from $1,000 to $2,000 annually. Cyclosporine, a powerful immunosuppressive responsible for much of the increased success of organ transplantation in the 1980s, may cost a patient anywhere from $5,000 to $7,000 for the first year, on the average.

Cost-effectiveness of Immunosuppressive Drugs

When discussing the methods of paying for immunosuppressive drug therapy, one must consider the issue of cost-effectiveness of this treatment. The question of cost-effectiveness is especially difficult in considering transplantation as a treatment for end-stage renal disease. The Task Force on Organ Transplantation stated that the "evidence is persuasive that kidney transplantation, when successful, is a less costly and more effective treatment modality than any form of renal dialysis." Further, the Task Force asserted that the patient also benefits by having fewer complications when cyclosporine is used.

The new Immunosuppressive Drug Therapy Block Grant established in this bill empowers each State to allocate funds to transplant centers for the purchase of immunosuppressive drugs. Each State will be allotted no less than $50,000 for each fiscal year from 1988 through 1990.

The Act allows for a degree of flexibility in making payments to States by allowing for the reallocation of unallotted funds at the close of a fiscal year.

Funds provided under part D of the Act may be used by the State to provide for the cost of immunosuppressive drugs which will be distributed to organ recipients by organ transplantation centers. The chief executive officer of each State is held accountable for providing to the Secretary annual progress reports on the State's organ procurement activities. The Secretary of the Department of Health and Human Services is required to submit an annual report to the Congress containing an analysis of the cost effects of the new program on various sectors, a description of the effect of part D on national organ procurement, and recommendations for the future.

III. Text of the Bill as Reported

[H.R. 3097, 100th Cong., 2d Session]

[Report No. 100-310]

AN ACT To amend the Public Health Service Act to revise and extend the program of assistance to organ procurement organizations, and for other purposes

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the "Organ Transplant Amendments Act of 1987".

SEC. 2. ASSISTANCE FOR ORGAN PROCUREMENT ORGANIZATIONS.

(a) Additional Grant Authority.—Section 371(a) of the Public Health Service Act (42 U.S.C. 273(a)) is amended—

(1) in paragraph (2), by inserting "consolidation," after "operation,";

(2) by redesignating paragraph (3) as paragraph (4) and inserting after paragraph (2) the following new paragraph:

"(3) The Secretary may make grants for special projects designed to increase the number of organ donors."; and

(3) in paragraph (4) (as redesignated in paragraph (2) of this subsection)—

(A) by striking "and" at the end of subparagraph (A);

(B) by striking the period at the end and inserting ", and"; and

(C) by adding at the end the following new subparagraph:

"(C) with respect to carrying out paragraph (3), give special consideration to proposals from existing organ procurement organizations.".

(b) Limitations on Additional Grant Authority.—Section 374(b)(3) of the Public Health Service Act (42 U.S.C. 274b(b)(3)) is amended in the first sentence by striking "section 371" and all that follows through "organizations" and inserting "paragraphs (2) and (3) of section 371(a)".

(c) Description of Organ Procurement Organization.—Section 371(b) of the Public Health Service Act (42 U.S.C. 273(b)) is amended—

(1) in paragraph (1)(E)—

(A) by striking "size which" and inserting "size such that"; and

(B) by striking "will include" and all that follows through "year" and inserting the following: "the organization can reasonably expect to procure organs from not less than fifty donors each year";

(2) in paragraph (2)(C), by striking "372(b)(2)(D)," and inserting the following: "372(b)(2)(E), including arranging for testing with respect to preventing the acquisition of organs that are infected with the etiologic agent for acquired immune deficiency syndrome,";

(3) in paragraph (2)(E)—

(A) by inserting "equitably" after "organs"; and

(B) by striking "centers and"; and

(4) in paragraph (2)—

(A) by striking "and" at the end of subparagraph (I);

(B) by striking the period at the end and inserting ", and"; and

(C) by adding at the end the following new subparagraph:

"(K) assist hospitals in establishing and implementing protocols for making routine inquiries about organ donations by potential donors.".

(d) AUTHORIZATIONS OF APPROPRIATIONS.—Section 371(c) of the Public Health Service Act (42 U.S.C. 273(c)) is amended to read as follows:

"(c) For grants under subsection (a), there is authorized to be appropriated $5,000,000 for each of the fiscal years 1988 through 1990.".

SEC. 3. ORGAN PROCUREMENT AND TRANSPLANTATION NETWORK.

(a) DUTIES.—Section 372(b)(2) of the Public Health Service Act (42 U.S.C. 274(b)(2)) is amended—

(1)(A) by redesignating subparagraphs (B) through (H) as subparagraphs (C) through (I), respectively; and

(B) by adding after subparagraph (A) the following new subparagraph:

"(B) establish membership criteria and medical criteria for allocating organs and provide to members of the public an opportunity to comment with respect to such criteria.";

(2) in subparagraph (D) (as redesignated in paragraph (1)(A) of this subsection), by striking "organs which" and all that follows and inserting "organs,";

(3) in subparagraph (E) (as redesignated in paragraph (1)(A) of this subsection), strike "organs," and insert the following: "organs, including standards for preventing the acquisition of organs that are infected with the etiologic agent for acquired immune deficiency syndrome,";

(4) in subparagraph (F) (as redesignated in paragraph (1)(A) of this subsection), by striking "basis," and inserting the following: "basis (and, to the extent practicable, among regions or on a national basis),"; and

(5)(A) by striking "and" at the end of subparagraph (H) (as redesignated in paragraph (1)(A) of this subsection);

(B) by striking the period at the end and inserting ", and"; and

(C) by adding at the end the following new subparagraph:

"(J) carry out studies and demonstration projects for the purpose of improving procedures for organ procurement and allocation.".

(b) CONSIDERATION OF CRITICAL COMMENTS.—Section 372 of the Public Health Service Act (42 U.S.C. 274) is amended by adding at the end the following new subsection:

"(c) The Secretary shall establish procedures for—

"(1) receiving from interested persons critical comments relating to the manner in which the Organ Procurement and

Transplantation Network is carrying out the duties of the Network under subsection (b); and

"(2) the consideration by the Secretary of such critical comments.".

SEC. 4. REQUIREMENT OF ESTABLISHMENT OF BONE MARROW REGISTRY.

(a) IN GENERAL.—Section 373 of the Public Health Service Act (42 U.S.C. 274a) is amended—

(1) by inserting "(a)" after the section designation; and

(2) by adding at the end the following new subsection:

"(b)(1) Not later than October 1, 1988, the Secretary shall, by grant or contract, establish a registry of voluntary bone marrow donors.

"(2) For the purpose of carrying out paragraph (1), there are authorized to be appropriated $1,500,000 for fiscal year 1989 and $1,600,000 for fiscal year 1990.".

(b) CONFORMING AMENDMENT.—Section 373 of the Public Health Service Act (42 U.S.C. 274a) is amended in the title by inserting "AND BONE MARROW REGISTRY" after "REGISTRY".

SEC. 5. ADMINISTRATION.

Section 375 of the Public Health Service Act (42 U.S.C. 274c) is amended—

(1) in the matter preceding paragraph (1), by striking "1985, 1986, 1987, and 1988," and inserting "1985 through 1990,"; and

(2) in paragraph (4), by striking "one year" and all that follows through "annual report" and inserting the following: "not later than April 1 of each of the years 1988 and 1990, submit to the Congress a report".

SEC. 6. REPORT.

Section 376 of the Public Health Service Act (42 U.S.C. 274d) is amended by striking "shall annually" and inserting the following: "shall, not later than October 1 of each year.".

SEC. 7. ESTABLISHMENT OF BLOCK GRANT PROGRAM.

(a) IN GENERAL.—Title XIX of the Public Health Service Act (42 U.S.C. 300w et seq.) is amended by adding at the end thereof the following new part:

"PART D—IMMUNOSUPPRESSIVE DRUG THERAPY BLOCK GRANT

"SEC. 1931. DEFINITIONS.

"For purposes of this part:

"(1) ELIGIBLE PATIENT.—The term 'eligible patient' means an organ transplant patient who is not eligible to receive reimbursement for the total cost of immunosuppressive drug therapy under title XVIII of the Social Security Act (42 U.S.C. 1395 et seq.), under the State's medicaid plan under title XIX of such Act (42 U.S.C. 1396 et seq.), or under private insurance.

"(2) IMMUNOSUPPRESSIVE DRUG THERAPY.—The term 'immunosupressive drug therapy' means drugs and biologicals that are to be used for the purpose of preventing the rejection of transplanted organs and tissues and that can be administered by the transplant patient.

"(3) TRANSPLANT CENTER.—The term 'transplant center' means a transplant center certified by a State under the laws and regulations of such State.

"SEC. 1932. AUTHORIZATION OF APPROPRIATIONS.

"For the purpose of making allotments to States to carry out this part, there are authorized to be appropriated $5,000,000 for each of the fiscal years 1988 through 1990.

"SEC. 1933. ALLOTMENTS.

"(a) AMOUNT.—

"(1) IN GENERAL.—From amounts appropriated under section 1932 for each of the fiscal years 1988 through 1990, the Secretary shall allot to each State an amount that bears the same ratio to the total amount appropriated under such section for such fiscal year as the total number of eligible patients in the States bears to the total number of eligible patients in the United States.

"(2) MINIMUM ALLOTMENT.—Notwithstanding paragraph (1), the allotment of any State in any fiscal year under this subsection shall not be less than $50,000. If, under paragraph (1), the allotment of any State in any fiscal year will be less than $50,000, the Secretary shall increase the allotment of such State to $50,000 and shall proportionately reduce the allotments of all other States whose allotment exceeds $50,000 in a manner that will insure that the allotment of each State in such fiscal year is at least $50,000.

"(b) UNALLOTTED FUNDS.—

"(1) IN GENERAL.—Subject to paragraph (2), to the extent that all the funds appropriated under section 1932 for a fiscal year and available for allotment in such fiscal year are not otherwise allotted to States because—

"(A) one or more States have not submitted an application or description of activities in accordance with section 1936 for such fiscal year;

"(B) one or more States have notified the Secretary that they do not intend to use the full amount of their allotment; or

"(C) some State allotments are offset or repaid under section 1906(b)(3) (as such section applies to this part pursuant to section 1936(d)):

such excess shall be allotted among each of the remaining States in proportion to the amount otherwise allotted to such States for such fiscal year without regard to this subsection.

"(2) ORGAN TRANSPLANT CENTERS.—

"(A) APPLICATION.—If a State does not submit an application for an allotment or description of activities in accordance with section 1936 for a fiscal year or notifies the Secretary that the State does not intend to use the full amount of the allotment of the State, an organ transplant center in the State may submit an application in accordance with section 1936 for the amount of the allotment not allocated to the State.

"(B) ALLOTMENT.—Subject to subparagraph (C), if an applicant center is approved by the Health Care Financing

Administration and the center complies with the requirements imposed on the State by this part, the Secretary shall provide to the center the amount of the allotment not allocated to the State.

"(C) MULTIPLE APPLICANTS.—If two or more applicant centers in a State meet the requirements of subparagraph (B), the Secretary shall divide among the eligible applicant centers in an equitable manner the amount of the allotment not allocated to the State.

"(D) DISTRIBUTION TO OTHER STATES.—If one or more centers in a State receive an allotment under this paragraph for a fiscal year, the allotment shall not be made available to remaining States under paragraph (1).

"SEC. 1934. PAYMENTS UNDER ALLOTMENTS TO STATES.

"(a) IN GENERAL.—For each fiscal year, the Secretary shall make payments, as provided by section 6503(a) of title 31, United States Code, to each State from its allotments under section 1933 from amounts appropriated for that fiscal year.

"(b) CARRYOVER FUNDS.—Any amount paid to a State for a fiscal year and remaining unobligated at the end of such year shall remain available for the next fiscal year to such State for the purposes for which it was made.

"SEC. 1935. USE OF ALLOTMENTS.

"(a) IN GENERAL.—

"(1) USE.—Except as provided in subsections (b) and (c), amounts paid to a State under section 1934 from its allotment under section 1933 for any fiscal year shall be used by the State to provide immunosuppressive drug therapy for eligible patients.

"(2) METHODS.—A State may use amounts paid to the State under section 1934 from its allotment under section 1933 to provide immunosuppressive drug therapy for eligible patients—

"(A) by purchasing the drugs and biologicals for such therapy and distributing such drugs and biologicals to transplant centers or eligible patients;

"(B) by certifying that an individual is an eligible patient for purposes of this part and by reimbursing a transplant center for the costs of immunosuppressive drug therapy provided by such center to such individual;

"(C) by any other method prescribed by the Secretary by regulation (other than the method described in subsection (b)(1)).

"(3) COPAYMENTS.—A State may require an eligible patient to whom immunosuppressive drug therapy is provided with amounts paid to the State under this part to make copayments for part of the costs of such therapy, without regard to section 1916 of the Social Security Act (42 U.S.C. 1396o).

"(b) LIMITATIONS.—A State may not use amounts paid to it under section 1934 to—

"(1) make direct payments to organ transplant patients; or

"(2) satisfy any requirement for the expenditure of non-Federal funds as a condition for the receipt of Federal funds.

"(c) ADMINISTRATIVE COSTS.—Not more than 10 percent of the total amount paid to any State under section 1934 from its allotment under section 1933 for any fiscal year may be used for administering the funds made available under section 1934. The State will pay from non-Federal sources the remaining costs of administering such funds.

"SEC. 1936. APPLICATION AND DESCRIPTION OF ACTIVITIES; REQUIREMENTS.

"(a) APPLICATION REQUIRED.—In order to receive an allotment for a fiscal year under section 1933, each State shall submit an application to the Secretary. Each such application shall be in such form and submitted by such date as the Secretary shall require. Each such application shall contain assurances that the State will meet the requirements of subsection (b).

"(b) REQUIREMENTS.—As part of the annual application required by subsection (a), the chief executive officer of each State shall—

"(1) certify that the State agrees to use the funds allotted to the State under section 1933 in accordance with the requirements of this part;

"(2) agrees to cooperate with Federal investigations undertaken in accordance with section 1907 (as such section applies to this part pursuant to subsection (d) of this section); and

"(3) certify that the State agrees that Federal funds made available under section 1934 for any period will be so used as to supplement and increase the level of State, local, and other non-Federal funds that would in the absence of such Federal funds be made available for the activities for which funds are provided under such section and will in no event supplant such State, local, and other non-Federal funds.

"(c) DESCRIPTION OF ACTIVITIES.—

"(1) IN GENERAL.—The chief executive officer of a State shall, as part of the application required by subsection (a), also prepare and furnish the Secretary (in accordance with such form as the Secretary shall provide) with a description of the intended use of the payments the State will receive under section 1934 for the fiscal year for which the application is submitted, including information on the programs and activities to be supported.

"(2) PUBLIC COMMENT.—The description shall be made public within the State in such manner as to facilitate comment from any person (including any Federal or other public agency) during development of the description and after its transmittal.

"(3) REVISIONS.—The description shall be revised (consistent with this section) throughout the year as may be necessary to reflect substantial changes in the programs and activities assisted by the State under this part. Any revision shall be subjected to paragraph (2).

"(d) ADMINISTRATION.—Unless inconsistent with this part, section 1903(b), section 1906(a), paragraphs (1) through (5) of section 1906(b), and sections 1907, 1908, and 1909 shall apply to this part in the same manner as such provisions apply to part A of this title.

"(e) ADDITIONAL INFORMATION.—Each annual report submitted by a State to the Secretary under section 1906(a) (as such section applies to this part pursuant to subsection (d) of this section) with respect to its activities under this part shall contain—

"(1) a specification of the number of eligible patients in the State receiving immunosuppressive drug therapy with amounts paid to the State under this part:

"(2) a description of the amount of any copayment required by the State under section 1935(a)(3); and

"(3) a certification that amounts paid to the State under this part are being used in accordance with this part.".

(b) REPORT.—

(1) IN GENERAL.—Not later than 24 months after the date of enactment of this Act, the Secretary of Health and Human Services shall prepared and transmit to the Congress a report concerning the impact of part D of title XIX of the Public Health Service Act (as added by section 7 of this Act).

(2) CONTENTS.—The report shall contain—

(A) a description of the effect of the program established under such part on organ transplants in the United States;

(B) an analysis of the effects of such program on the costs of organ transplants and renal dialysis;

(C) an analysis of the extent to which amounts paid to States under such part are used for purposes other than the purposes specified by such part, including an analysis of the extent to which drugs and biologicals purchased with such amounts are provided to individuals who are not eligible patients under such part; and

(D) such recommendations as the Secretary considers appropriate, including recommendations as to whether financial assistance under such program should be continued during fiscal years after fiscal year 1990.

(c) CONFORMING AMENDMENTS.—

(1) IN GENERAL.—The matter following subparagraph (D) of section 1902(a)(10) of the Social Security Act (42 U.S.C. 1396a(a)(10)(D)) is amended—

(1) by striking out "and" at the end of subclause (VIII); and

(2) by inserting before the semicolon at the end thereof the following; ", and (X) the making available of immunosuppressive drug therapy (or immunosuppressive drugs) to individuals who have received organ transplants shall not, by reason of this paragraph, require the making available of any other type of drug or the making availablle of any drugs for other individuals".

(2) APPLICATION OF AMENDMENTS.—The amendments made by subsection (a) shall apply to drugs furnished after the date of the enactment of this Act.

IV. COMMITTEE VIEWS

The National Organ Transplant Act of 1984 (P.L. 98-507) authorized grants for the planning, establishment, initial operation and expansion of local organ procurement organizations (OPO). The

purpose of this grant authority was to improve the availability of organs for transplantation and to enhance the efficiency of organ retrieval efforts. The Committee intended that these grants be used to establish OPOs in unserved areas, to consolidate or replace agencies when more than one was serving an area, and to improve the effectiveness of exisitng OPOs. P.L. 98-507 provided authorizations of $5 million in 1985, $8 million in 1986, and $12 million in 1987. Funds were not appropriated in FY 1985, and only $2.6 million and $3 million were appropriated in FY 1986 and FY 1987 respectively.

The Committee believes that the authorization of appropriations for these grants should be extended for three more years, in order to fulfill their original objectives. The Committee has also concluded that emphasis should be given to the consolidation of overlapping agencies and to improvements in existing agencies. Therefore, H.R. 3097 would extend the authorization of appropriations for three years, at a level of $5 million per year. The bill would also make it clear that grants can be awarded for the purpose of consolidating existing, overlapping agencies and may be awarded to existing agencies for special projects designed to increase the number of organs retrieved by an agency. These grants would be subject to the limitations in current law that they not exceed two years in duration, and not exceed $500,000 in a year or $800,000 over two years.

The bill would also clarify the service area that must be encompassed by an approved OPO. Current law provides that the service area must be large enough to include at least fifty potential donors (unless it is an entire state and does not satisfy that requirement). The Committee bill would revise this to require that the service area be large enough that it is reasonable to expect the agency to procure organs from at least 50 donors. Since organs are not always retrieved from all of the potential donors, this revision will have the effect, in some instances, of requiring a larger service area than would be the case under current law. According to a study done for the Department of Health and Human Services agencies on average are currently procuring organs from only 44 donors. (Because more than one organ may be obtained from a donor, the average number of organs obtained per agency is about 110.) The Committee expects the Secretary to make the appropriate judgment whether it is reasonable to expect the agency to procure organs from at least 50 donors. This requirement is important not only in determining whether an OPO is eligible for a grant, but also whether it is qualified to be designated as an OPO under section 9318 of OBRA 1986.

The bill would also clarify the Committee's intent that the OPO is responsible for allocating organs equitably among the patients who are in need of a transplant. The waiting lists for organs have lengthened and concerns have been raised that OPOs might be in a position to show favoritism to patients of a particular transplant facility. Although the Committee is not aware of any specific instance of such favoritism, it expects the Secretary to monitor of the allocation of organs closely.

The bill would also require OPOs to make sure tests are performed on retrieved organs to determine that they are free of the

AIDS virus and to assist hospitals in complying with the requirement of Section 9318 of OBRA 1986 that the hospitals have protocols for making routine inquiries regarding potential donors. Again, these OPO responsibilities are prerequisities not only for qualifying for grants under this authority, but also for designation under Section 9318.

The Organ Procurement and Transplant Network (OPTN) was created by the 1984 Act in order to facilitate an equitable allocation of organs among patients. Among its responsibilities are the development of medical criteria for the proper allocation of organs and the adoption of quality standards for the acquisition and transportation of organs. Under Section 9318 of OBRA '86, the OPTN performs a critical role in assuring quality of care, since a hospital performing transplants must become a member of the OPTN and abide by its policies in order to participate in Medicare and Medicaid. This provision was intended to protect transplant patients by assuring equitable access to the limited supply of organs and by assuring that transplants are performed in accordance with acceptable medical practice. The Committee expects the OPTN to develop appropriately broad criteria for membership, based on medical judgments regarding the factors that influence successful outcomes.

The OPTN's responsibilities are great and the purposes of the Act will be served only if the policies of the OPTN are sound and are soundly developed. The allocation of organs may well be a life-or-death decision for patients. Denial of membership in OPTN may adversely affect patient access to transplantation or may force a hospital to forgo providing transplant services. It is critical, therefore, that the OPTN's policies represent a broad consensus of expert medical judgment and that these policies be developed openly, with full opportunity for participation by all interested parties. The bill would require that the OPTN articulate its membership criteria and its medical criteria for the allocation of organs, and that it give all interested parties, including patients, physicians, and hospitals, an opportunity to review and comment on these criteria. It is the Committee's intent that the OPTN undertake this process for its existing criteria and that it do so whenever changes in the criteria are under consideration. The Committee also urges the OPTN to arrange for public comment at least once a year, even if no changes are proposed, and expects the Department of Health and Human Services to follow closely and review these criteria. The OPTN should replicate as closely as possible the process followed by such agencies as the Health Care Financing Administration in promulgating regulations, including the use of a public hearing on issues of major consequence and potential controversy.

H.R. 3097 includes another provision designed to assure that the OPTN is responsive to the concerns of parties affected by its policies and operation. The Secretary would be required to establish procedures for receiving and considering comments critical of the OPTN's performance of its statutory responsibilities. The Secretary would be expected to publicize the availability of this process and to seek to resolve with the OPTN any problems raised that he concludes have merit.

The bill would add to the OPTN's current duties the responsibility to adopt and use standards for protecting organ recipients

against transmission of the AIDS virus. It would also clarify that, *in addition to its other defined tasks, the OPTN may use funds* made available under this authority to carry out special studies and projects designed to improve organ procurement and allocation. These would have to be agreed upon by the Secretary as part of the contract with the OPTN. The purpose is to permit the OPTN and the Secretary to take advantage of unique opportunities to collect and evaluate data.

The bill would also clarify and refine two aspects of the existing responsibilities of the OPTN. The OPTN is currently required to assist OPOs in the distribution of organs "which cannot be placed within the service areas of the organizations". This phrase is deleted, so as to remove any statutory bias respecting the important question of criteria for the proper distribution of organs among patients. The OPTN, through the public process outlined above, should resolve any issues regarding the fair and effective distribution of organs. Patient welfare must be the paramount consideration. The Committee does not wish the statute to be read as establishing a preference for, or against, distribution within the service area of the OPO. Similarly, the bill would remove any implied limitation on the OPO's authority to prepare and distribute blood sera for determining compatibility of organ and recipient. The OPTN, at its discretion, could do so on a regional, inter-regional, or national basis.

Bone marrow transplantation is now the treatment of choice for several blood diseases. For the transplant to be successful, however, characteristics of the donor and the recipient must be matched precisely. Consequently, most transplants to date have been done between siblings or other family members. Unfortunately, only about one-third of the patients who could benefit from a transplant have such an appropriate donor within the immediate family. Several transplant centers have begun to perform transplants between individuals that are not related, but whose blood characteristics are appropriately matched.

About 160 transplants using unrelated matched donors have been done in the world to date. According to a staff paper prepared by the Office of Technology Assessment at the request of the Committee, the preliminary data on these transplants is promising, and it is clear that lives are being saved. (Bone Marrow Transplantation Using Unrelated Donors: Current Clinical Status and Policy Issues, October 1987). The OTA report indicates that greater success could be expected with improvements in the matching of donors and recipients, with reductions in the waiting period for transplants, and with other improvements in the procedure growing out of continuing research. However, the ability of these centers to perform transplants with unrelated, matched donors, and to conduct thorough research on the best techniques for such procedures, has been seriously hampered by their difficulty in identifying appropriate donors. According to the OTA report, a registry of volunteer potential donors would facilitate transplantations of greater numbers of patients. The report also concludes that there are no major technical barriers to establishing and maintaining such a registry.

The Naval Medical Research Institute, of the U.S. Navy, has established a national registry of bone marrow donors, pursuant to a directive from the Senate Appropriations Committee (S. Rept. 98–636). The Office of Naval Research has contracted with a consortium of organizations to develop and maintain the registry. The consortium includes the American Red Cross, the American Association of Blood Banks, and the Council of Community Blood Centers. These organizations work with a group of over 50 local blood banks and blood centers that have established lists of tissue-type blood donors. Under the contract, a central coordinating center performs computer-based searches for potential donors, using data supplied by the local blood centers about the tissue type of persons who have volunteered to be included in the registry. The coordinating center performs additional functions, including: maintaining records; conducting research on the determinants of successful transplants; and facilitating communication and transfer of bone marrow between blood centers and transplant centers. Safeguards to preserve donor confidentiality and informed consent are built into the process. In addition, the coordinating center has developed standards which participating transplant centers must meet, in order to assure that high quality care is provided and procedures are performed in a manner consistent with accepted medical practice.

The primary purpose of the registry is to support civilian bone marrow transplant programs. The Navy has indicated its willingness to maintain responsibility for the registry through FY 1988 (subject to funds being appropriated for that purpose), but would prefer to transfer that responsibility to another agency beginning FY 1989. The Committee believes the Department of Health and Human Services is the appropriate agency to assume responsibility for such a registry.

The Committee bill would require the Secretary of HHS to establish a registry of voluntary bone marrow donors, under a contract or grant with an appropriate organization or organizations, no later that October 1, 1988. It would authorize appropriations of $1.5 million in FY 1988 and $1.6 million in FY 1990 for this purpose.

The Committee expects the Secretary to determine whether participation in the registry by transplant centers should be limited to those that are conducting research on bone marrow transplantation pursuant to an approved research protocol. This would require the Secretary to determine the appropriate balance between the two functions, both vital, which would be served by the registry: assisting in the treatment of patients and facilitating research. The OTA staff paper discusses the relationship between these two functions and the concerns raised by interested parties. The Committee expects both functions to be served and directs the Secretary to evalute carefully the relative emphasis to be given to each.

The Secretary could place lead responsibility for the registry with the Office of Organ Transplantation, with the National Institutes of Health, or with another office or agency of the department. However, if NIH does not have lead responsibility, it should maintain a strong coordination role in order to assure that the research potential of the registry is tapped.

The bill would not impose any specific requirements on the registry, or otherwise direct the Secretary on how this registry should be carried out. The Committee clearly intends, however, that the registry operate in a manner that preserves donor confidentiality and informed consent. The Committee further intends that the registry maintain rigorous standards limiting participation by transplant centers to those that are performing these procedures in accordance with accepted medical practice and that agree to share informtion on their results. The Secretary could continue the arrangement established under the current Navy contract, but is not mandated to do so.

The 1984 Act required the Secretary to maintain, through 1988, an administration unit in the Public Health Service to administer and coordinate the authorities established therein. It also required the Secretary to submit to the Congress an annual report on the status of organ donation and coordination services. No date for submission of the report was stated and the Secretary has not submitted a report since the report of the Task Force on Organ Transplantation was released in April 1986.

The Committee bill would extend the requirement for an administrative unit for two years, through 1990. It would also eliminate the requirement for an annual report for 1988 and 1990.

The Secretary is also required to publish an annual report on the scientific and clinical status of organ transplantation. No such report has been released. The Committee directs the Secretary to produce and publish this report on an annual basis. This report should be coordinated and produced by the Office of Organ Transplantation.

Of the approximately 8000 patients receiving organ transplants annually, an estimated one quarter have no insurance coverage for the immunosuppressive drugs needed to successfully sustain the transplant. Such drugs are extremely costly. The cost of the most effective immunosuppressive drug, cyclosporine, may be as high as $10,000 per year for a transplant patient. In most cases, if the patient cannot afford the immunosuppressive drugs, the patient is not considered a candidate for the transplant. In some cases, patient are transplanted, but must rely on less effective, cheapter drugs that will increase the rejection rate as much as 50 percent. This problem will undoubtedly increase now that the federal government has determined that some heart and liver transplants are no longer experimental. The amendment added to H.R. 3097 to provide funds to states for immunosuppressive drugs is intended to improve access to organ transplantation.

Newer immunosuppressive drugs, such as cyclosporine, are currently reimbursed under Medicare Parts A and B because they require professional administration. Nonetheless, new products such as this may present reimbursement concerns due to their relatively high cost, because the patient is required to pay a certain portion of medical coverage through copayments and deductibles. This may shift incentives toward less desirable and possibly less cost effective therapeutic alternatives. Those potential reimbursement problems are not addressed in this legislation but may need attention in the near future. The Committee encourages further examination of those issues to determine whether additional action is necessary,

through regulation or legislation. The Committee is interested in assuring adequate coverage for immunosuppressive therapy regardless of the treatment setting.

In addition, the Committee encourages a continuing review of the reimbursement situation in the context of State Medicaid programs. To guarantee safe and effective treatment of acture transplant rejection it may be necessary to alter Medicaid policies and practices to some extent in order to mitigate the effects of high co-payment burdens.

While this legislation is earmarked to assist with the health care cost of organ transplantation, the Committee feels that this legislation is markedly different from the Black Lung and End Stage Renal Disease programs which it has been compared to. First, this legislation authorizes a fixed sum instead of being open-ended like those programs. Second, unlike other programs which have no potential of saving money, this program has the real potential of reducing federal outlays because organ transplantation may be less costly than more traditional forms of medical care such as renal dialysis or extended hospital stays in intensive care units. Third, instead of providing first-dollar coverage, funding under this legislation is only available when the patient has another funding source for the transplant operation itself.

This legislation authorizes $5 million a year, for three years, in the form of a grant to States for the purpose of purchasing self-administered drugs. Allotments shall be made to each state from the total amount appropriated in proportion to the total number of eligible patients in that state. In any event, the minimum amount available in any fiscal year to each state shall be $50,000. Should a state not apply for these funds, one or more transplant centers approved by the Health Care Financing Administration may apply for the state's allotment. Funds paid to a state but not obligated in a fiscal year may be carried over to the next fiscal year. All organ transplant patients whose immunosuppressive drugs are not fully covered by existing private or public programs are eligible for assistance under this grant program, though the extent of assistance may be based on the individual's ability to pay. The Committee is aware that Congress is currently considering proposals for a comprehensive catastrophic insurance program. If such proposals are enacted, they may eliminate the need for the program established by this legislation. The Committee will determine whether to continue the program at that time.

States have three options for administering the immunosuppressive drug funding program. They may purchase the drugs, and make them available to transplant centers or eligible patients, or they may reimburse the transplant centers for the cost of the drugs provided to patients whom the State has certified as eligible. Third, a State may administer this program in a different manner, if approved by the Secretary.

The legislation does not prevent States from requiring patients to pay part of the cost of their immunosuppressive drugs provided under this program. The Committee anticipates that any program of co-payments established by the State will be carefully designed to reflect individual patients' ability to make out-of-pocket payments.

Since this legislation was designed, and the authorization level established to fill gaps in funding for Federal, State and private sources, it includes a requirement that funds provided under this Act shall not supplant State programs to fund immunosuppressive drugs. This would be a basis for denial of a State's participation in the grant program.

The Committee recognizes that organ transplantation is a rapidly changing field. Therefore, the Secretary is required to report to the Congress, within 24 months after enactment of the legislation, on its implementation and effects on the cost, patient selection, and number of organs transplanted. This report, along with the required Secretarial recommendation, will assist the Committee in determining whether to modify, terminate, or extend the program after fiscal year 1990. The Secretary may choose to combine this report with the required report from the Office of Organ Transplantation.

In addition to cyclosporine, the Committee recognizes the need for coverage under this grant program for the cost of other self-administered immunosuppressive drugs such as prednisone and azathioprine.

V. Committee Action

H.R. 3097 was referred to the Committee on Labor and Human Resources on October 28, 1987, following passage by the House of Representatives. The bill was considered before the Committee on March 2, 1988, and reported favorably with an amendment offered by Senators Hatch and Kennedy on an immunosuppressive drug block grant program by a unanimous vote.

VI. Votes in Committee

H.R. 3097 was reported favorably by the Committee on Labor and Human Resources on March 2, 1988, by unanimous vote.

U.S. Congress,
Congressional Budget Office,
Washington, DC, March 10, 1988.

Hon. Edward M. Kennedy,
Chairman, Committee on Labor and Human Resources,
U.S. Senate, Washington, DC.

Dear Mr. Chairman: The Congressional Budget Office has prepared the attached cost estimate for H.R. 3097, the Organ Transplant Amendments Act of 1987, as ordered reported by the Senate Committee on Labor and Human Resources on March 2, 1988.

If you wish further details on this estimate, please call me or have your staff contact Lori Housman (226-2820).

Sincerely,

James Blum, *Acting Director.*

Attachment.

CONGRESSIONAL BUDGET OFFICE COST ESTIMATE

1. Bill number: H.R. 3097.
2. Bill title: Organ Transplant Amendments Act of 1987.

3. Bill status: As ordered reported from the Senate Committee on Labor and Human Resources, March 2, 1988.

4. Bill purpose: The purpose of this bill is to revise and extend through 1990 the program of assistance to organ procurement organizations under the Public Health Service Act. This bill is subject to subsequent appropriations action.

5. Estimated cost to the Federal Government:

[By fiscal years, in millions of dollars]

	1988	1989	1990	1991	1992	1993
Grants for organ procurement organization.						
Authorization level	3.6	5.0	5.0			
Estimated outlays	2.0	3.9	4.7	2.2	0.7	0.1
Administration:						
Estimated authorization level		1.5	1.6			
Estimated outlays		1.3	1.6	.2		
Bone marrow registry:						
Authorization level		1.5	1.6			
Estimated outlays		1.3	1.6	.2		
Immunosuppressive Drug Therapy Block Grant Program:						
Authorization level	5.0	5.0	5.0			
Estimated outlays	2.8	4.4	4.9	2.2	.6	.1
Bill total:						
Estimated authorization level	8.6	13.0	13.2			
Estimated outlays	4.8	10.9	12.8	4.8	1.3	.2

The costs of this bill would fall within budget function 550.

Basis of estimate: H.R. 3097, the Organ Transplant Amendments Act of 1987, authorizes $5 million for each of the fiscal years 1988 through 1990 for grants for qualified organ procurement organization for planning, establishment and initial operation. Because $1.4 million has already been appropriated for fiscal year 1988 for these grants, H.R. 3097 would authorize an additional $3.6 million for 1988. In addition, the bill also extends the authorization of an administrative unit within the Public Health Service to coordinate organ procurement activities in fiscal years 1989 and 1990. Authorization levels for the administrative unit for 1989 and 1990 have been estimated by increasing the 1988 appropriation by the appropriate inflator.

A third provision requires the Secretary of Health and Human Services to establish a bone marrow transplant registry. Authorization levels for the registry are set at $1.5 million for fiscal year 1989 and $1.6 million for fiscal year 1990.

A final provision requires the Secretary of Health and Human Services to establish an Immunosuppressive Drug Therapy Block Grant program for fiscal years 1988 through 1990 authorized at $5 million in each of these years.

Authorizations for fiscal years 1989 and 1990 are assumed to be fully appropriated at the beginning of each fiscal year. Outlays for the grants, the administrative unit, and the registry are estimated using spendout rates calculated by CBO on the basis of recent program data. Outlays for the Immunosuppressive Drug Therapy Block Grant are estimated based on similar block grant spending information.

6. Estimated cost to state and local government: States participating in the Immunosuppressive Drug Therapy Block Grant program may spend up to 10 percent of funds received to administer the program. States would have to fund additional administrative costs from non-federal funds. The bill specifically states that funds provided should be used to supplement and not supplant state funding.

7. Estimate comparison: None.

8. Previous CBO estimate: CBO previously prepared an estimate for H.R. 3097 as ordered reported by the House Committee on Energy and Commerce on October 6, 1987. The bill was considered by the House Committee prior to the 1988 appropriation. The Senate estimate reflects amounts authorized in excess of the amounts already appropriated for fiscal year 1988. The Senate bill also adds a provision for the Immunosuppressive Drug Therapy Block Grant program for 1988, 1989 and 1990.

9. Estimate prepared by: Lori Housman.

10. Estimate approved by: James L. Blum, Assistant Director for Budget Analysis.

VIII. Regulatory Impact Statement

The Committee has determined that there will be minimal or no increase in regulatory burden of paperwork imposed by this bill.

IX. Section-by-Section Analysis

H.R. 3097—Organ Transplant Amendments Act of 1987

As reported by the Senate Committee on Labor and Human Resources:

Section 1 of the bill cites the Act as the "Organ Transplant Amendments Act of 1987".

Section 2(a) of the bill amends Section 371(a) of the Public Health Service Act and authorizes the Secretary of Health and Human Services to make grants for the consolidation of those qualified organ procurement organizations registered with the Organ Procurement and Transplantation Network (OPTN), and for special projects designed to increase the number of organ donors. Special consideration for these grant awards will be given to existing organ procurement organizations to accomplish the goal of increasing the number of organ donors and to consolidate qualified organ procurement organizations.

Section 2(b) of the bill amends Section 374(b)(3) of the Public Health Service Act and provides that the Secretary make one grant per organ procurement organization serving the same service area for those special projects designed to increase the number of organ donors and for the consolidation of organ procurement organizations. Under the current law, such grants may be made for two years.

Section 2(c) amends Section 371(b) of the Public Health Service Act by clarifying the service area for organ procurement organizations. The bill provides that a qualified organ procurement organization have a defined service area which is a geographical area of sufficient size such that the organization can reasonably expect to

procure organs from not less than fifty donors each year. In addition, the bill requires that organ procurement organizations shall arrange for testing with respect to preventing the acquisition of organs that are infected with the etiologic agent for the acquired immune deficiency syndrome. Further, the bill requires organ procurement organizations to implement a system for the equitable distribution of organs among transplant candidates. A new section (K) is added to require organizations to assist in establishing and implementing protocols for making routine inquiries about organ donations by potential donors.

Section 2(d) of the bill amends Section 371(c) of the Public Health Service Act to authorize the appropriation of $5,000,000 for each of the fiscal years 1988 through 1990.

Section 3(a) of the bill amends Section 372(b)(2) of the Public Health Service Act by adding to the current duties of the Organ Procurement and Transplantation Network (OPTN). The bill requires the OPTN to establish membership criteria and medical criteria for allocating organs and to provide members of the public an opportunity to comment with respect to such criteria. This section is also amended to ensure that the OPTN adopt standards for the acquisition and transportation of donated organs including standards for preventing the acquisition of organs that are infected with the etiologic agent for the acquired immune deficiency syndrome. In addition, the OPTN is required to prepare and distribute, on a regional or national basis, samples of blood sera from individuals who are included on the list of potential organ recipients, and whose immune system makes it difficult for them to receive organs. This provision is expected to facilitate matching potential recipients with organ donors. Another provision of the bill, section (J), requires the OPTN to conduct studies and demonstration projects for the purpose of improving procedures for organ procurement and allocation.

Section 3(b) amends Section 372 of the Public Health Service Act by adding a new subsection which requires the Secretary to establish procedures for (1) receiving from interested persons critical comments relating to the manner in which the OPTN carries out the duties of the Network under Section 372 of the Public Health Service Act, and (2) the consideration by the Secretary of such critical comments.

Section 4(a) amends Section 373 of the Public Health Service Act by requiring the Secretary to establish a registry of voluntary bone marrow donors no later than October 1, 1988. Appropriations for the bone marrow registry are authorized at $1,500,000 for fiscal year 1989 and $1,600,000 for fiscal year 1990.

Section 5 of the bill amends Section 375 of the Public Health Service Act by requiring the Secretary to designate and maintain an identifiable administrative unit in the Public Health Service to deal with organ procurement matters for the years 1985 through 1990, and to submit a report to the Congress no later than April 1, 1988, and April 1, 1990.

Section 6 amends Section 376 of the Public Health Service Act to require the Secretary ro report on the scientific and clinical status of organ transplantation no later than October 1 of each year.

Section 7 of the bill amends Title XIX of the Public Health Service Act by adding a new part D—Immunosuppressive Drug Therapy Block Grant.

Under the new part D, Section 1931 defines three terms used in the legislation: (1) "eligible patient" means an organ transplant patient who is not eligible to receive reimbursement for the total cost of immunosuppressive drug therapy under Medicare, Medicaid, or private insurance; (2) "immunosuppressive drug therapy" means drugs and biologicals that are used to prevent the rejection of transplanted organs and tissues and that are administered by the transplant patient; and (3) "transplant center" means a transplant center certified by a State under its laws and regulations.

Section 1932 authorizes appropriations of $5,000,000 for each of the fiscal years 1988 through 1990 for allotments to States.

Section 1933(a) describes the manner in which an allotment will be made to each State from the amounts appropriated under section 1932. The allotment shall be an amount bearing the same ratio to the total amount appropriated as the total number of eligible patients in the State bears to the total number of eligible patients in the U.S. The total allotment of any State under this section shall not be less than $50,000 a year. If any State would receive less than $50,000, the Secretary will increase the State's allotment to $50,000 and proportionately reduce the allotments of all other States so that all States receive at least $50,000. The section also provides for the reallotment of funds when: (A) one or more States have not submitted an application or description of activities in accordance with section 1936; (B) one or more States have notified the Secretary they do not intend to use the full amount of their allotment; or (C) some State allotments are offset or repaid under section 1906(b)(3) of the Public Health Service Act as it applies to this part. Any excess of unallotted funds shall be allotted among each of the remaining States in proportion to the amount otherwise allotted to those States for the fiscal year.

If a State does not apply for an allotment or notifies the Secretary that it does not intend to use the full amount of its allotment, an organ transplant center in the State may submit an application for the amount of the allotment not allocated to the State. The Secretary is directed to provide an applicant center with the amount of the allotment not allocated to the State if the applicant center is approved by the Health Care Financing Administration and complies with State requirements. If two or more applicant centers in a State meet the requirements for allotment, they are eligible to receive equitable portions of the amount of the allotments not allocated to the State. Amounts allotted to such centers in a State shall not be made available for reallotment to other States.

Section 1934(a) directs the Secretary to make payments to each State from its allotments under section 1933 from amounts appropriated for that fiscal year. Under section 1934(b) any amount paid to a State for a fiscal year and remaining unobligated at the end of such year shall remain available for the next fiscal year to the State for whose purposes it was originally intended.

Section 1935(a) provides that States shall use their allotments to provide immunosuppressive drug therapy for eligible patients. The three methods by which a State may provide such therapy include:

(A) purchasing the drugs and biologicals and distributing them to transplant centers or eligible patients; (B) certifying that an individual is an eligible patient and reimbursing a transplant center for the costs of immunosuppressive drug therapy provided by the center to the patient; or (C) any other method prescribed by the Secretary. A State may require an eligible patient to make copayments for part of the costs of such therapy.

A State may not use its allotment to make direct payments to organ transplant patients or to satisfy any requirement for the expenditure of non-Federal funds as a condition for the receipt of Federal funds. Not more than 10 percent of a State's allotment may be used for administrative costs.

Under section 1936(a) each State must submit an application to the Secretary in order to receive an allotment for a fiscal year under section 1933. Each such application shall be submitted by such date and in such form as required by the Secretary.

Section 1936(b) provides that as part of the annual application the chief executive of each State is require to: (1) certify that the State agrees to use the funds allotted to it under section 1933 in accordance with the requirements of this part; (2) cooperate with Federal investigations undertaken in accordance with section 1907 of the PHS Act; and (3) certify that the State agrees that Federal funds made available under section 1934 will be used to supplement and increase the level of State, local, and other non-Federal funds that would otherwise be made available, and will in no event supplant such funds.

Section 1936(c) requires the chief executive of a State, as part of the required application, to prepare and furnish the Secretary with a description of the intended use of funds received under this part, including information on programs and activities to be supported. The description must be made public in the State in such a manner as to facilitate comment during development of the description and after its transmittal. The description shall be revised throughout the year as may be necessary to reflect substantial changes in programs and activities assisted by the State under this part.

Section 1936(d) provides that certain administrative provisions concerning block grants, set forth in part A of Title XIX of the PHS Act (Preventive Health and Health Services Block Grant), shall also apply to this part.

Section 1936(e) directs that the annual reports submitted by the States to the Secretary under section 1906(a) shall contain: (1) a specification of the number of eligible patients in the State receiving immunosuppressive drug therapy with amounts paid to the State under this part; (2) a description of the amount of any copayment required by the State under section 1935(a)(3); and (3) a certification that amounts paid to the State under this part are being used in accordance with the part.

The Secretary is required to prepare and transmit to the Congress a report concerning the impact of this new part. The report shall contain (a) a description of the effect of the program on organ transplants in the United States; (b) an analysis of the effects of the program on the costs of organ transplants and renal dialysis; (c) an analysis of the extent to which amounts paid to States under this part are used for purposes other than the purposes specified,

including an analysis of the extent to which drugs and biologicals purchased with such amounts are provided to individuals who are not eligible patients under this part; and (d) such recommendations as the Secretary considers appropriate, including recommendations as to whether financial assistance under this program should be continued after fiscal year 1990.

Section 1902(a)(10) of the Social Security Act (Medicaid provisions) is amended to provide that the making available of immunosuppressive drug therapy to individuals who have received organ transplants shall not, by reason of this provision, require the making available of any other type of drug or the making available of any drugs for other individuals.

This new block grant shall apply to drugs furnished after the date of the enactment of this Act.

X. Additional Views

ADDITIONAL VIEWS OF MR. QUAYLE

I must reluctantly express my views against the Committee amendment to this bill which provides for Federal funding of immunosuppressive drugs. Rapid advances in medical technology have led to serious questions of economics and equity. These questions are exemplified by the issues surrounding organ transplantation and in the amendment which this Committee has—unwisely in my view—decided to approve. As legislators, we cannot consider issues such as organ transplantation and related matters in isolation from other significant health problems that compete for our limited resources.

While I sympathize with those individuals who require immunosuppressive drugs, particularly those who are uninsured, I am unable to support this amendment because I believe it represents unsound Federal health policy, initiating a precedent that Congress will find almost impossible to deal with in a rational fashion.

The Federal government does not pay the health care bills of individuals who cannot afford to pay them unless they are covered by Medicare or Medicaid. This Committee knows too well that many in this country have no health insurance at all—some 37 million. For several years now, Congress and the Reagan Administration have been grappling with how to get insurance to those who cannot afford to pay for their health care, whether it is coverage for catastrophic acute care expenses of Medicare beneficiaries, long term nursing home care, catastrophic care for chronically ill children, or just basic coverage to those without any insurance at all. A few hundred dollars of health care charges can be a catastrophic event to a poor individual or family not covered by Medicaid. About one third of all uninsured individuals have incomes below the Federal poverty level. Certainly, the needs of these individuals are equally as critical as those of transplant patients.

Looking more narrowly at catastrophic drug costs, this legislation selects one specific illness and one set of therapeutic agents which are politically attractive for special treatment. In my view, this raises a serious question of equity. I cannot justify singling out immunosuppressive drugs when there are other expensive drugs needed by many individuals with life-threatening illnesses. I think we need to ask why establishing a grant program to pay for the drugs needed by transplant patients is more worthwhile than paying for costly hypertensive or cancer drugs which a Medicare patient may need to sustain his or her life? The proponents of this bill offer no rational explanation of why the government should pay the bills for immunosuppressive drugs rather than those of other equally worthy claimants.

H.R. 3097 establishes a policy that the Federal government will pay for something simply because it is expensive. If one is to carry out this line of reasoning, why not just pass legislation which will require the Federal government to bear the cost for the most expensive diseases?

The Federal government's history of assuming the burden of payment for particular diseases suggests the need for reflection. I believe that it is in the best interest of Congress to examine some past history before deciding to enact this bill into law. Although the majority views express otherwise, I feel that a look at both the history of the Black Lung Program and the End Stage Renal Disease Programs in this regard is instructive.

The Black Lung Program was originally enacted as Title IV of the Federal Coal Mine Health and Safety Act of 1969 (P.L. 91-173) to compensate coal miners disabled as a result of an ailment known as "black lung" or pneumoconiosis caused by the inhalation of coal dust. This program has been amended a variety of times. A review of the legislative history of this program reveals that its initial sponsors promised that it was a "one shot" deal; the sponsors of the immunosuppressive block grant are suggesting similarly that this proposal may just be a temporary measure. Let me quote one of the original sponsors of the Black Lung Program:

> This is a one-shot effort. This is not a continuing compensation arrangement to establish Federally based compensation for this or any other industry. We are only taking on those who are now afflicted with pneumoconiosis in its fourth stage—complicated pneumoconiosis.

I would suggest that we all look at the fact that the scope of this one time only program now goes beyond the mere "chronic dust disease of the lung arising out of employment in a coal mine" to now include just about any "impairment" due to work in a coal mine.

A look at the original cost estimates of this program is also useful. When confronted with a cost estimate by the Social Security Administration that the original program would cost $355 million annually, one of the major sponsors of the program, Mr. Dent stated: "Why, if we gave full compensation to every ex-coal miner and a fur coat to every widow, it could not cost more than $40 or $50 million." Do I need to remind my colleagues that at the end of Fiscal Year 1987, the Federal cost of the program is expected to be $1.6 billion and that the Black Lung Trust Fund is expected to have a deficit of $2.9 billion? This is the fruit of the Federal government's first approach to funding the costs of a specific disease.

Our second venture was the End Stage Renal Disease Program, a program which has become similarly inflated. Originally estimated to cost $250 million a year, the program cost about $2.2 billion in 1987 for all services provided.

The majority views attempt to distinguish this bill from previous "single disease" programs. Only brief reflection is needed to show that the Committee's distinctions are, in the colloquial, a distinction without a difference.

DAN QUAYLE.

XI. Changes in Existing Law

In compliance with rule XXVI paragraph 12 of the Standing Rules of the Senate, the following provides a print of the statute or the part or section thereof to be amended or replaced (existing law proposed to be omitted is enclosed in black brackets, new matter is printed in italic, existing law in which no change is proposed is shown in roman):

Public Health Service Act

* * * * * * *

TITLE III—GENERAL POWERS AND DUTIES OF PUBLIC HEALTH SERVICE

* * * * * * *

Part H—Organ Transplants

ASSISTANCE FOR ORGAN PROCUREMENT ORGANIZATIONS

SEC. 371. (a)(1) The Secretary *may make grants for the planning* of qualified organ procurement organizations described in subsection (b).

(2) The Secretary may make grants for the establishment, initial operation, *consolidation, and expansion* of qualified organ procurement organizations described in subsection (b).

(3) The Secretary may make grants for special projects designed to increase the number of organ donors.

[(3)] *(4)* In making grants under paragraph (1) and (2), the Secretary shall—

(A) take into consideration any recommendations made by the Task Force on Organ Transplantation established under section 101 of the National Organ Transplant Act, [and]

(B) give special consideration to applications which cover geographical areas which are not adequately served by organ procurement organizations[.] *and*

(C) with respect to carrying out paragraph (3), give special consideration to proposals from existing organ procurement organizations.

(b)(1) A qualified organ procurement organization for which grants may be made under subsection (a) is an organization which, as determined by the Secretary, will carry out the functions described in paragraph (2) and—

(A) * * *

* * * * * * *

(E) has a defined service area which is a geographical area of sufficient [size which] *size such that* (unless the service area

comprises an entire State) [will include at least fifty potential organ donors] *the organization can reasonably expect to procure organs from not less than fifty donors* each year and which either includes an entire standard metropolitan statistical area (as specified by the Office of Management and Budget) or does not include any part of such an area,

* * * * * * *

(2) An organ procurement organization shall—

(A) * * *

* * * * * * *

(C) arrange for the acquisition and preservation of donated organs and provide quality standards for the acquisition of organs which are consistent with the standards adopted by the Organ Procurement and Transplantation Network under section [372(b)(2)(D),] *372(b)(2)(E), including arranging for testing with respect to preventing the acquisition of organs that are infected with the etiologic agent for acquired immune deficiency syndrome,*

* * * * * * *

(E) have a system to allocate donated organs *equitably* among transplant [centers and] patients according to established medical criteria,

* * * * * * *

(I) have arrangements to cooperate with tissue banks for the retrieval, processing, preservation, storage, and distribution of tissues as may be appropriate to assure that all usable tissues are obtained from potential donors, [and]

(J) evaluate annually the effectiveness of the organization in acquiring potentially available organs[.], *and*

(K) assist hospitals in establishing and implementing protocols for making routine inquiries about organ donations by potential donors.

[(c) For grants under subsection (a) there are authorized to be appropriated $5,000,000 for fiscal year 1985, $8,000,000 for fiscal year 1986, and $12,000,000 for fiscal year 1987.]

(c) For grants under subsection (a), there is authorized to be appropriated $5,000,000 for each of the fiscal years 1988 through 1990.

ORGAN PROCUREMENT AND TRANSPLANTATION NETWORK

SEC. 372. (a) The Secretary shall by contract provide for the establishment and operation of an Organ Procurement and Transplantation Network which meets the requirements of subsection (b). The amount provided under such contract in any fiscal year may not exceed $2,000,000. Funds for such contracts shall be made available from funds available to the Public Health Service from appropriations for fiscal years beginning after fiscal year 1984.

(b)(1) * * *

(2) The Organ Procurement and Transplantation Network shall—

(A) establish in one location or through regional centers—

(i) a national list of individuals who need organs, and

(ii) a national system, through the use of computers and in accordance with established medical criteria, to match organs and individuals included in the list, especially individuals whose immune system makes it difficult for them to receive organs,

(B) establish membership criteria and medical criteria for allocating organs and provide to members of the public an opportunity to comment with respect to such criteria,

[(B)] *(C)* maintain a twenty-four-hour telephone service to facilitate matching organs with individuals included in the list,

[(C)] *(D)* assist organ procurement organizations in the distribution of [organs which cannot be placed within the service areas of the organizations,] *organs,*

[D] *(E)* adopt and use standards of quality for the acquisition and transportation of donated organs, *including standards for preventing the acquisition of organs that are infected with the etiologic agent for acquired immune deficiency syndrome,*

[E] *(F)* prepare and distribute, on a regionalized [basis,] *basis (and, to the extent practicable, among regions or on a national basis),* samples of blood sera from individuals who are included on the list and whose immune system makes it difficult for them to receive organs, in order to facilitate matching the compatibility of such individuals with organ donors,

[F] *(G)* coordinate, as appropriate, the transportation of organs from organ procurement organizations to transplant centers,

[G] *(H)* provide information to physicians and other health professionals regarding organ donation, [and]

[H] *(I)* collect, analyze, and publish data concerning organ donation and transplants[.], *and*

(J) carry out studies and demonstration projects for the purpose of improving procedures for organ procurement and allocation.

(c) The Secretary shall establish procedures for—

(1) receiving from interested persons critical comments relating to the manner in which the Organ Procurement and Transplantation Network is carrying out the duties of the Network under subsection (b); and

(2) the consideration by the Secretary of such critical comments.

SCIENTIFIC REGISTRY AND BONE MARROW REGISTRY

SEC. 373. *(a)* The Secretary shall, by grant or contract, develop and maintain a scientific registry of the recipients of organ transplants. The registry shall include such information respecting patients and transplant procedures as the Secretary deems necessary to an ongoing evaluation of the scientific and clinical status of organ transplantation. The Secretary shall prepare for inclusion in the report under section 376 an analysis of information derived from the registry.

(b)(1) Not later than October 1, 1988, the Secretary shall, by grant or contract, establish a registry of voluntary bone marrow donors.

(2) For the purpose of carrying out paragraph (1), there are authorized to be appropriated $1,500,000 for fiscal year 1989 and $1,600,000 for fiscal year 1990.

GENERAL PROVISIONS RESPECTING GRANTS AND CONTRACTS

SEC. 374. (a) No grant may be made under section 371 or 373 or contract entered into under section 372 or 373 unless an application therefor has been submitted to, and approved by, the Secretary. Such an application shall be in such form and shall be submitted in such manner as the Secretary shall by regulation prescribe.

(b)(1) * * *

* * * * * * *

(3) Grants under [section 37 for the establishment, initial operation, or expansion of organ procurement organizations] *paragraphs (2) and (3) of section 371(a)* may be made for two years. No such grant may exceed $500,000 for any year and no organ procurement organization may receive more than $800,000 for initial operation or expansion.

* * * * * * *

ADMINISTRATION

SEC. 375. The Secretary shall, during fiscal years [1985, 1986, 1987, and 1988,] *1985 through 1990,* designate and maintain an identifiable administrative unit in the Public Health Service to—

(1) * * *

* * * * * * *

(4) [one year after the date on which the Task Force on Organ Transplantation transmits its final report under section 104(c) of the National Organ Transplant Act, and annually thereafter through fiscal year 1988, submit to Congress an annual report] *not later than April 1 of each of the years 1988 and 1990, submit to the Congress a report* on the status of organ donation and coordination services and include in the report an analysis of the efficiency and effectiveness of the procurement and allocation of organs and a description of problems encountered in the procurement and allocation of organs.

REPORT

SEC. 376. The Secretary [shall annually] *shall, no later than October 1 of each year,* publish a report on the scientific and clinical status of organ transplantation. The Secretary shall consult with the director of the National Institutes of Health and the Commissioner of the Food and Drug Administration in the preparation of the report.

* * * * * * *

TITLE XIX—BLOCK GRANTS

* * * * * * *

PART D—IMMUNOSUPPRESSIVE DRUG THERAPY BLOCK GRANT

DEFINITIONS

SEC. 1931. For purposes of this part:

(1) ELIGIBLE PATIENT.—The term "eligible patient" means an organ transplant patient who is not eligible to receive reimbursement for the total cost of immunosuppressive drug therapy under title XVIII of the Social Security Act (42 U.S.C. 1395 et seq.), under the State's medicaid plan under title XIX of such Act (42 U.S.C. 1396 et seq.), or under private insurance.

(2) IMMUNOSUPPRESSIVE DRUG THERAPY.—The term "immunosuppressive drug therapy" means drugs and biologicals that are to be used for the purpose of preventing the rejection of transplanted organs and tissues and that can be administered by the transplant patient.

(3) TRANSPLANT CENTER.—The term "transplant center" means a transplant center certified by a State under the laws and regulations of such State.

AUTHORIZATION OF APPROPRIATIONS

SEC. 1932. For the purpose of making allotments to States to carry out this part, there are authorized to be appropriated $5,000,000 for each of the fiscal years 1988 through 1990.

ALLOTMENTS

SEC. 1933. (a) AMOUNT.—

(1) IN GENERAL.—From amounts appropriated under section 1932 for each of the fiscal years 1988 through 1990, the Secretary shall allot to each State an amount that bears the same ratio to the total amount appropriated under such section for such fiscal year as the total number of eligible patients in the state bears to the total number of eligible patients in the United States.

(2) MINIMUM ALLOTMENT.—Notwithstanding paragraph (1), the allotment of any State in any fiscal year under this subsection shall not be less than $50,000. If, under paragraph (1), the allotment of any State in any fiscal year will be less than $50,000, the Secretary shall increase the allotment of such State to $50,000 and shall proportionately reduce the allotments of all other States whose allotment exceeds $50,000 in a manner that will insure that the allotment of each State in such fiscal year is at least $50,000.

(b) UNALLOTTED FUNDS.—

(1) IN GENERAL.—Subject to paragraph (2), to the extent that all the funds appropriated under section 1932 for a fiscal year and available for allotment in such fiscal year are not otherwise allotted to States because—

(A) one or more States have not submitted an application or description of activities in accordance with section 1936 for such fiscal year;

(B) one or more States have notified the Secretary that they do not intend to use the full amount of their allotment; or

(C) some State allotments are offset or repaid under section 1906(b)(3) (as such section applies to this part pursuant to section 1936(d));

such excess shall be allotted among each of the remaining States in proportion to the amount otherwise allotted to such States for such fiscal year without regard to this subsection.

(2) ORGAN TRANSPLANT CENTERS.—

(A) APPLICATION.—If a State does not submit an application for an allotment or description of activities in accordance with section 1936 for a fiscal year or notifies the Secretary that the State does not intend to use the full amount of the allotment of the State, an organ transplant center in the State may submit an application in accordance with section 1936 for the amount of the allotment not allocated to the State.

(B) ALLOTMENT.—Subject to subparagraph (C), if an applicant center is approved by the Health Care Financing Administration and the center complies with the requirements imposed on the State by this part, the Secretary shall provide to the center the amount of the allotment not allocated to the State.

(C) MULTIPLE APPLICANTS.—If two or more applicant centers in a State meet the requirements of subparagraph (B), the Secretary shall divide among the eligible applicant centers in an equitable manner the amount of the allotment not allocated to the State.

(D) DISTRIBUTION TO OTHER STATES.—If one or more centers in a State receive an allotment under this paragraph for a fiscal year, the allotment shall not be made available to remaining States under paragraph (1).

PAYMENTS UNDER ALLOTMENTS TO STATES

SEC. 1934. (a) IN GENERAL.—For each fiscal year, the Secretary shall make payments, as provided by section 6503(a) of title 31, United States Code, to each State from its allotments under section 1933 from amounts appropriated for that fiscal year.

(b) CARRYOVER FUNDS.—Any amount paid to a State for a fiscal year and remaining unobligated at the end of such year shall remain available for the next fiscal year to such State for the purposes for which it was made.

USE OF ALLOTMENTS

SEC. 1935. (a) IN GENERAL.—

(1) USE.—Except as provided in subsections (b) and (c), amounts paid to a State under section 1934 from its allotment under section 1933 for any fiscal year shall be used by the State to provide immunosuppressive drug therapy for eligible patients.

(2) METHODS.—A State may use amounts paid to the State under section 1934 from its allotment under section 1933 to provide immunosuppressive drug therapy for eligible patients—

(A) by purchasing the drugs and biologicals for such therapy and distributing such drugs and biologicals to transplant centers or eligible patients;

(B) by certifying that an individual is an eligible patient for purposes of this part and by reimbursing a transplant center for the costs of immunosuppressive drug therapy provided by such center to such individual;

(C) by any other method prescribed by the Secretary by regulation (other than the method described in subsection (b)(1)).

(3) COPAYMENTS.—A State may require an eligible patient to whom immunosuppressive drug thereapy is provided with amounts paid to the State under this part to make copayments for the part of the costs of such therapy, without regard to section 1916 of the Social Security Act (42 U.S.C. 1396).

(b) LIMITATIONS.—A State may not use amounts paid to it under section 1934 to—

(1) make direct payments to organ transplant patients; or

(2) satisfy any requirement for the expenditure of non-Federal funds as a condition for the receipt of Federal funds.

(c) ADMINISTRATIVE COSTS.—Not more than 10 percent of the total amount paid to any State under section 1934 from its allotment under section 1933 for any fiscal year may be used for administering the funds made available under section 1934. The State will pay from non-Federal sources the remaining costs of administering such funds.

APPLICATION AND DESCRIPTION OF ACTIVITIES; REQUIREMENTS

SEC. 1936. (a) APPLICATION REQUIRED.—In order to receive an allotment for a fiscal year under section 1933, each State shall submit an application to the Secretary. Each such application shall be in such form and submitted by such date as the Secretary shall require. Each such application shall contain assurances that the State will meet the requirements of subsection (b).

(b) REQUIREMENTS.—As part of the annual application required by subsection (a), the chief executive officer of each State shall—

(1) certify that the State agrees to use the funds allotted to the State under section 1933 in accordance with the requirements of this part;

(2) agrees to cooperate with Federal investigations undertaken in accordance with section 1907 (as such section applies to this part pursuant to subsection (d) of this section); and

(3) certify that the State agrees that Federal funds made available under section 1934 for any period will be so used as to supplement and increase the level of State, local, and other non-Federal funds that would in the absence of such Federal funds be made available for the activities for which funds are provided under such section and will in no event supplant such State funds and other non-Federal funds.

(c) DESCRIPTION OF ACTIVITIES.—

(1) IN GENERAL.—The chief executive officer of a State shall, as part of the application required by subsection (a), also prepare and furnish the Secretary (in accordance with such form

as the Secretary shall provide) with a description of the intended use of the payments the State will receive under section 1934 for the fiscal year for which the application is submitted, including information on the programs and activities to be supported.

(2) PUBLIC COMMENT.—The description shall be made public within the State in such manner as to facilitate comment from any person (including any Federal or other public agency) during development of the description and after its transmittal.

(3) REVISIONS.—The description shall be revised (consistent with this section) throughout the year as may be necessary to reflect substantial changes in the programs and activities assisted by the State under this part. Any revision shall be subject to paragraph (2).

(d) ADMINISTRATION.—Unless inconsistent with this part, section 1903(b), section 1906(a), paragraphs (1) through (5) of section 1906(b) and sections 1907, 1908, and 1909 shall apply to this part in the same manner as such provisions apply to part A of this title.

(e) ADDITIONAL INFORMATION.—Each annual report submitted by a State to the Secretary under section 1906(a) (as such section applies to this part pursuant to subsection (d) of this section) with respect to its activities under this part shall contain—

(1) a specification of the number of eligible patients in the State receiving immunosuppressive drug therapy with amounts paid to the State under this part;

(2) a description of the amount of any copayment required by the State under section 1935(a)(3); and

(3) a certification that amounts paid to the State under this part are being used in accordance with this part.

○